

REMARKS

Claims 39-40 were alleged to be directed to inventions that are independent or distinct from the invention originally claimed. Specifically, these claims were said to be "drawn to two new and distinct methods of using the said composition." Office Action, page 2. Contrary to the Examiner's position, claims 39-40 are not drawn to methods of using a composition, but are akin to previously examined claims 35-36, which are drawn to methods of formulating hydrocortisone.

Even if claims 39-40 are independent and distinct from the previously examined claims, examination of claims 39-40 would not pose an undue burden. The Examiner has not provided any explanation, let alone classifications of the allegedly independent or distinct methods embraced by the claims that would cause an undue burden in terms of searching or examination. For example, there is no evidence of record showing that a search that includes a method of formulating hydrocortisone by mixing said hydrocortisone with a pentylene glycol (as in claim 35) would not also be substantially, if not completely, co-extensive with a search for a method of enhancing solubility of hydrocortisone by formulating hydrocortisone in pentylene glycol (as in claim 39).

To the contrary, Applicants respectfully submit that there would be no undue burden to the Examiner in examining the full scope of the claimed invention in its entirety. Thus, Applicants request that claims 39-40 be examined.

Claims 16-38 were again rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Castro* in view of *Cooper*, in view of *Quigley*, and further in view of *Vollhardt*.

Applicants reiterate their arguments of record. There is no teaching or suggestion in the cited references, taken individually or collectively, that the solubility of

hydrocortisone or a derivative thereof is greater in pentylene glycol than in any other solvent, or that the bioavailability of hydrocortisone is enhanced in pentylene glycol relative to homologous glycols.

Even assuming, *arguendo*, that a *prima facie* case of obviousness has been established, the Examiner has ignored the unexpected results which are discussed in the specification. The Examiner has repeatedly sidestepped the evidence of unexpected results which are shown in the specification, instead choosing to focus exclusively on the Fares Declaration.

Objective evidence of secondary considerations, e.g., unexpected results, is relevant to the issue of obviousness, and it must be considered in every case in which it is submitted, regardless of whether it is presented in the specification, by counsel or via affidavit or declaration. See, M.P.E.P. § 2145 (September 6, 2007 at 2100-162) (*citing In re Soni*, 34 U.S.P.Q.2d 1684, 1687 (Fed. Cir. 1996) (error not to consider evidence presented in the specification)). The Examiner has failed to put forth any reasoning as to why the unexpected results presented in the specification, either alone or in combination with the Fares Declaration, are not sufficient to overcome a *prima facie* case of obviousness. Clearly, the Examiner has failed to consider all the evidence of record. Accordingly, Applicants once again request consideration of the evidence along with this response.

As described in the present specification, the claimed invention achieves several unexpected results. These results flow from Applicants' underlying discovery that hydrocortisone and its derivatives are more soluble in pentylene glycol than other polyols such as glycerol, propylene glycol, butylene glycol and hexylene glycol, which so happen to be taught in Quigley and Cooper. More specifically, as shown in Example 1 on page 11, Applicants discovered that hydrocortisone is about two

times more soluble in pentylene glycol than in hexylene glycol, about 1.5 times more soluble in pentylene glycol than in propylene glycol, and about 1.25 times more soluble in pentylene glycol than in butylene glycol. There are no teachings or suggestions in *Quigley* or *Cooper* to these effects. As taught in the present specification, there are at least three unexpected benefits that flow from the combination of pentylene glycol and hydrocortisone and its derivatives, namely aesthetic appeal, less tackiness and greater bioavailability. The first two advantages are described on pages 5-6 as follows:

Due to the greater solubility of the active agents in pentylene glycol, the amounts of the other solvents are significantly lower, e.g., about 20 to 95 percent less than if pentylene glycol were not present. Relatively high amounts of glycols are undesirable from several standpoints, especially in terms of aesthetic appeal and tackiness. In contrast, compositions of the present invention are more aesthetically acceptable and have less tackiness.

In Example 7 on pages 16-18 of the specification, Applicants compared the rate of release of hydrocortisone from various commercially available one percent hydrocortisone anti-itch creams and ointments. The results show that the release rate of hydrocortisone from a gel of the present invention was about 100 times greater than the commercial products, none of which contains pentylene glycol. As described in paragraph 34 on page 18, and illustrated in Fig. 1, the results also show that the compositions of the present invention provided greater availability of the active agent to penetrate the affected area on the skin or scalp, and thus provided greater bioavailability of the active agent.

As attested to by Dr. Fares, these results would not have been expected based on the collective teachings of the prior art. By specifically limiting the diols to C3, C4 and/or C6 diols, *Cooper* and *Quigley* are believed to teach away from the

claimed invention. *Vollhardt's* primary objective was to increase water resistance or in other words, the amount of time that a sunscreen agent actually stays on the surface of the skin. *Vollhardt* does teach that his invention can also be practiced with antioxidants, anti-inflammatory compounds, anti-microbial compounds, antiperspirants, fragrances and skin whitening compounds. See columns 4-5. Hydrocortisone is thus merely one of many, many other of *Vollhardt's* less preferred active agents, leaving one skilled in the art to pick and choose from a myriad of combinations in order to arrive at the presently claimed invention.

In view of the foregoing, Applicants respectfully request reconsideration of the presently claimed invention, including newly added claims 39 and 40, in view of the evidence contained in the specification as elaborated upon in the Fares Declaration. Applicants submit that the presently claimed invention defines a patentable contribution to the art. Accordingly, reconsideration and withdrawal of the rejection and allowance of claims 16-40, are respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

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If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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